

Introduction

Congratulations for helping your teenager stop using drugs! Your teenager is invited to take part in a study of a test medication called Suboxone. This clinic is studying whether Suboxone and Subutex, together with counseling, helps teenagers and young adults stop using heroin and related drugs (called opioids). The clinic is part of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN), which aims to improve drug treatment across the nation.

More about Suboxone and Subutex

Suboxone is a pill that contains two different medicines, buprenorphine and naloxone. Subutex only contains buprenorphine. Buprenorphine is a medication that is used to prevent the withdrawal symptoms people experience when they stop using opioid drugs. These symptoms can include depressed mood, anxiety, drug craving, nausea, diarrhea, vomiting, muscle and joint aches, muscle spasm, runny nose and eyes, sweating and difficulty sleeping. Naloxone is a medicine that reverses the effects of opioids, and it can cause withdrawal symptoms. Giving naloxone and buprenorphine together in Suboxone may make it easier to use each medicine properly. The U.S. Food and Drug Administration has approved Suboxone for individuals 16 and older. Everyone in the study will get all the usual services given at this clinic including counseling twice or more each week. Everyone will also get Suboxone treatment. Half of the people will take Suboxone for 7-14 days and half will take Suboxone for three months. This study will find out which way of using Suboxone is most helpful.

There are other types of drug treatment available at this clinic that do not include Suboxone, so your child does not have to be in the study to get treatment. If you choose not to enroll your child in this study, your child can still get all the other available treatment services at this clinic if eligible.

What do I need to know as a parent or legal guardian?

Teenagers under the age of 18 must have their parent or legal guardian give written permission to be in the study. This is called informed consent. However, teenagers must also give "their own" written permission to take part (assent). A staff person will discuss all the details of the study with you and your child, and you will be given a chance to ask any questions that may help you decide whether to allow your child to take part.

You and your child will be asked to give permission for two separate parts of the study. The first part is called a screening and it checks to see if your child meets the study requirements and can take the study medicine. There are certain research criteria for participation. The screening involves:

- Blood and urine tests to check for drugs and general health
- A pregnancy test for females
- A physical exam by a doctor or nurse practitioner
- Electrocardiogram and alcohol breath test
- Questions about your child's health, mood and behavior
- Questions about your child's drug use and previous treatments

If the screening indicates that your child can take part, we will offer you the study and request written permission for the treatment part of the study. Before you and your child provide permission to take part, you both will have to pass a quiz showing that you understand what is involved.

If you decide to allow your child to join the study, here is what you can expect:

1. Because this is a study, the researchers will assign patients to one of the Suboxone treatment groups. Patients will be assigned to groups by chance, (like flipping a coin). Neither you nor your child will get to choose which Suboxone treatment your child will receive. Everyone in the study will get

drug counseling and will come to weekly research visits to check the effect of treatment for three months. Everyone will continue with study visits after the three months.

- **Group 1.** Patients take Suboxone for 7-14 days. The dose of Suboxone will gradually get smaller over the 7-14 days.
 - **Group 2.** Patients will take Suboxone for three months. The dose of Suboxone will gradually get smaller during the third month.
2. The doctor or nurse will teach your child how to take the medicine. In most cases, your child will have to come to the clinic to get each tablet of medicine. For the first few days, your child will have to stay in the clinic for up to three hours. During this time, the doctors will check to see how your child reacts to the medicine so they can find the right dose. On the rest of the days, your child will be able to leave the clinic after taking their medicine, unless there are additional study tasks to do for that day. Your child should not drive or operate heavy machinery until they have adjusted to the effects of the medicine.
 3. The doctor will watch your child closely while they are taking the medicine, to make sure they are taking it correctly and to see how they are doing. The doctor may give your child other medicines if needed for withdrawal symptoms (for example, nausea, diarrhea, or trouble sleeping).
 4. For the first three months of the study, your child will need to come to the clinic once per week for research visits lasting 10-15 minutes. These can be scheduled at the same time that they come for their medicine. Please keep the site staff informed about any changes in your contact information such as telephone number. During those visits, the following things will happen:

- Urine test to check for drugs
- Pregnancy test if female and taking medicine
- Breath test to check for alcohol
- Questions about medicine use
- Questions about how they are doing

5. For the first three months, your child will also need to take part in one individual and one group counseling session each week. After that, your child's counselor will decide how often they should come for counseling. We hope you and your child will also attend family counseling as well as self-help groups for kids their age.
6. Your child will also need to come to the clinic for longer research visits at six other times during the study. These visits will take place 1, 2, 3, 6, 9, and 12 months after starting Suboxone. The visits may last up to 2.5 hours. During those visits, some or all of the following things will happen:
 - Blood tests for general health check
 - Urine test to check for drugs
 - Breath test to check for alcohol
 - Physical exam for general health check
 - Questions about medicine use
 - Questions about how they are doing
7. Even if your child decides to stop taking Suboxone or to stop coming to the counseling sessions, we would like them to come to each of the research visits so we can continue to check how they are doing. Please keep the study staff informed of any changes in your contact information. Your child will be paid for the time and effort it takes to attend these research visits. **PAYMENTS WILL NOT BE MADE IN CASH.** Instead, payment will be made in vouchers, certificates for merchandise, or other form.

Questions about the study

These are the answers to some questions about the study that may help you and your child decide if they should take part.

1. How long will my child be in the study?

The study will last for one year. Your child will come to the clinic weekly for three months, and at 6, 9, and 12 months after taking their first dose of medicine.

2. How many people will take part in the study?

About 240 people across the country will be in the study.

3. What will my child have to do during the study?

There are a few things your child will have to do if they join the study, including:

- Take the medicine as directed. In most cases this will require daily visits to the clinic.
- Attend all research visits and fill out some questionnaires
- Give urine and blood samples
- Call the clinic if they have any side effects or health problems

4. Can girls who are able to get pregnant take part in the study?

Yes, but only if they take steps to avoid getting pregnant. We don't know if Suboxone harms an unborn child. If your daughter is sexually active, she will have to use birth control while taking Suboxone. If your daughter is not sexually active, they will be able to be in the study without using birth control, but they will still have a urine pregnancy test performed. Your daughter will have pregnancy tests several times during the study to make sure that she is not pregnant while taking the medicine. If you or your daughter thinks she may be pregnant, make sure to tell the study doctor right away.

Note: In some states, researchers and medical staff are not allowed to discuss the results of pregnancy tests with parents of adolescent children. Other types of information about your child may also be protected. The study and clinic staff will follow the rules of this state. The study coordinator at your child's clinic can inform you of the relevant state laws.

5. What will my child get for taking part in this study?

The Suboxone will be provided for free, and it may help your child to stop using drugs. Being in the study will give your child more contact with clinic staff. This extra attention from doctors, nurses and counselors may help your child.

6. Will my child have any bad effects from taking part in the study?

Any medicine can have unwanted or bad effects. The possible bad effects of Suboxone will be discussed with you and your child before they start the study. There will also be a list of bad effects on the paper you and your child will read and sign before starting the study. Some of the possible bad effects of Suboxone and Subutex include irritation in the mouth, headache, changes in sleep (too tired or can't sleep), nausea, constipation and dizziness. Other kinds of bad effects, including liver damage, could also occur.

Serious bad effects, including overdose or death, can occur if your child continues to use heroin, other drugs (especially drugs like Valium or Xanax), or alcohol while they are on the study medicine. Buprenorphine itself may cause physical dependence. It can also cause intoxication and mild respiratory depression. If your child stops taking it abruptly, they may experience opioid withdrawal symptoms. They may also be more sensitive to the effects of opioids when they detoxify from heroin, Buprenorphine/Naloxone or other opioids. When your child first starts taking the pills, they may become tired, uncoordinated and/or have clouded thinking. As a safety precaution, they should not drive or operate machinery until they get used to these effects or the effects go away. Bad effects can also occur if your child uses the medicine in a way other than what was intended.

The study doctor will check your child for side effects each time they come to a study visit. You or your child should call the study doctor if your child has any problems with the medicines.

Bad effects can also happen if your child continues to abuse opioids and does not receive treatment.

7. Will anyone see my child's private information?

Much of the information collected during this study is personal and private. There is a very small risk that

people not involved in the study might see your child's information. The study staff are trained to keep your child's information private. Your child's name will not be on any information that leaves this clinic, and private information will not be shared, except in certain cases. Some institutions that are involved with the study are allowed to look at your child's information, including the National Institute on Drug Abuse, the Department of Health and Human Services, and research review committees working with your clinic and study staff. Individuals at these institutions will not reveal your child's name or private information. Certain types of information must be reported to authorities and will not be kept private. The study staff must report suspected child abuse or neglect. They must also report if they think your child is a risk to themselves or others. In some states, study staff must also report it if your child has a communicable disease, such as HIV/AIDS or hepatitis.

8. What if I don't want my child to join the study?

Since your child is under 18, they cannot be in the study without your written permission. If your child refuses to provide written permission, they can not be forced to be in the study. If your child does not take part in the study, they can still receive treatment at this clinic in the usual manner.

For More Information

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Further information on the Clinical Trials Network can be accessed through the NIDA website at

www.drugabuse.gov

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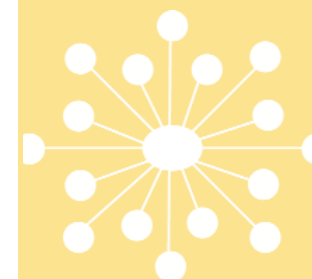
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National Drug Abuse Treatment

Clinical Trials Network

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a Narcotics
Treatment
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Teenager

*Forging partnerships to
improve the quality of
drug abuse treatment
throughout the nation . . .*



National Institutes of Health
U.S. Department of Health and Human Services